HEMOCHRON® Jr. *Signature+*

Whole Blood Microcoagulation System

Operator's Manual

English

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This manual is published by International Technidyne Corporation (ITC) for use with the HEMOCHRON Jr. *Signature+* Whole Blood Microcoagulation System.

Questions or comments regarding the contents of this manual can be directed to the address at the back of this manual or to your ITC representative.

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INTENDED USE

The HEMOCHRON Jr. *Signature+* Whole Blood Microcoagulation System is a battery-operated, hand-held instrument that performs individual point-of-care coagulation tests on fresh or citrated whole blood. These tests include: Activated Clotting Time (ACT+ and ACT-LR), Activated Partial Thromboplastin Time (APTT and APTT Citrate), and Prothrombin Time (PT and PT Citrate). The system is intended to be used with test cuvettes that are available from ITC.

Data management capabilities are included with the instrument. These capabilities include storage of up to 400 patient results and 400 quality control results, designation of quality control levels, tagging of test results with date and time, entry of Patient ID and/or Operator ID, and printing of results.

HEMOCHRON *Configuration Manager* software is included. This software allows the user to connect a personal computer to an instrument and perform system configuration functions using the fast and convenient Microsoft® Windows® user interface. ITC data management software programs, provided separately, allow the user to connect a personal computer to an instrument and perform various data management and data reporting functions. Refer to the operating instructions for these programs for information on use in conjunction with the HEMOCHRON Jr. *Signature+*.

For *in vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Events that lead to formation of a blood clot are simplified in coagulation theory into two interactive coagulation cascades that are referred to as the **intrinsic** and the **extrinsic** pathways.

The clotting factors involved in these pathways are numbered I through V and VII through XIII. The intrinsic pathway begins with the contact activation of factor XII and, through the interaction of several coagulation factors, results in the conversion of soluble fibrinogen to insoluble fibrin strands. The extrinsic pathway is initiated through the interaction of tissue factor with factor VII. Platelets, essential co-factors in this reaction, provide the platelet phospholipid (PF3) surface on which coagulation reactions occur.

Heparin is used to maintain hemostasis during cardiac surgery and percutaneous coronary interventional (PCI) procedures. However, its administration can pose significant risk to the patient since individual patients can vary as much as twelve-fold in heparin sensitivity. Overdosing heparin can result in dangerous bleeding, and underdosing heparin can lead to thrombosis. Therefore, monitoring heparin therapy is vital in guarding against these undesirable side effects.

Activated Clotting Time (ACT+ and ACT-LR), Activated Partial Thromboplastin Time (APTT and APTT Citrate), and Prothrombin Time (PT and PT Citrate) tests are general coagulation screening tests that are used to measure the functionality of the blood coagulation cascade. The ACT test is the method of choice for monitoring heparin therapy during cardiac surgery and PCI. Fresh whole blood is added to an activator (Celite®, silica, kaolin, or glass particles), and then timed for the formation of a clot. The type of activator used will affect the degree of prolongation of the ACT to a given heparin dose.

The HEMOCHRON Jr. ACT+ test uses a mixture of silica, kaolin, and phospholipids as an activator to create a rapid and highly sensitive alternative to existing ACT tests. This test demonstrates linearity at heparin concentrations ranging from 1.0 to 6.0 units of heparin per mL of blood, and it is not affected by high dose aprotinin therapy.

The HEMOCHRON Jr. ACT-LR test uses a Celite activator due to its excellent heparin sensitivity. The test demonstrates linearity at heparin concentrations up to 2.5 units of heparin per mL of blood. The test is not intended for use with aprotinin therapy.

The HEMOCHRON Jr. APTT test measures the intrinsic coagulation pathway and involves all coagulation factors except factors VII and III (tissue factor). The APTT test improves the PTT test through use of a contact activating substance, which standardizes activation of Factor XII to provide a more precise and sensitive assay for low level heparin monitoring. The HEMOCHRON Jr. APTT test is formulated to provide optimal heparin sensitivity at heparin concentrations up to 1.5 units of heparin per mL of blood.

The HEMOCHRON Jr. APTT Citrate test performs the same measurement as the APTT test, using a citrated whole blood sample.

The HEMOCHRON Jr. PT test measures the extrinsic coagulation pathway and is sensitive to coagulation factors VII, X, V, II, and fibrinogen. PT results may be abnormal in patients with liver disease or Vitamin K deficiency. The test is widely used to monitor oral anticoagulant therapy. The PT test is a unitized test system utilizing a highly sensitive thromboplastin for improved specificity and sensitivity.

The HEMOCHRON Jr. PT Citrate test performs the same measurement as the PT test, using a citrated whole blood sample.

PRINCIPLES OF OPERATION

The HEMOCHRON Jr. *Signature+* Whole Blood Microcoagulation System provides many features for ease of use and reliability, including a patented clot detection system, a data storage module, interfaces for a laboratory computer and/or printer, and a streamlined user-interface panel.

The system measures whole blood clotting times using HEMOCHRON Jr. disposable single-use cuvettes. Each cuvette contains all of the reagents necessary for a specified test.

The operator inserts a cuvette for the test into the instrument and then enters information about the sample (if desired). After the cuvette has warmed to 37 °C ±1.0 °C, the instrument beeps, signaling the operator that a blood sample can be added to the cuvette and the test started.

The operator then places a drop of blood in the sample well of the cuvette and presses the **START** key. The instrument measures the required volume of blood and automatically moves it into the cuvette test channel, where it is mixed with reagents. The remainder of the blood sample, not needed for testing, is automatically drawn out of the sample well and into an enclosed waste channel on the cuvette.

After mixing with the reagent, the sample is moved back and forth at a predetermined rate within the test channel and monitored for clot formation. The test channel is maintained at 37 °C ±1.0 °C during the test.

The rate of movement of the sample is monitored by a series of LED optical detectors that are aligned with the test channel. When the blood clots, the flow of the blood sample within the test channel is impeded, reducing its rate of flow between the optical detectors.

This reduction in flow below a predetermined value signals to the instrument that a clot has formed. The instrument also emits an audible beep when clot formation occurs, indicating the end of the test. An internal timer measures the elapsed time between the start of the test and the clot formation. During the test, the whole blood clotting time (in seconds) is displayed.

APTT and APTT Citrate results are displayed as plasma equivalent (PE) values, and PT and PT Citrate results are displayed as the International Normalized Ratios (INR) and PE values. ACT+ and ACT-LR results are displayed as Celite ACT equivalent time.

The results will remain on the display while the cuvette remains in the instrument.

The result can be automatically printed along with the time and date the test was run, the Patient ID, Operator ID, and other information, if entered. The result is also saved in an internal database. Up to 400 patient test results and 400 quality control test results can be stored on the instrument for later printing or downloading.

Individual HEMOCHRON Jr. *Signature+* instruments can be customized so that designated quality control tests must be performed whenever a specified period of time has elapsed. The instruments can also be configured so that only authorized operators can operate the system and/or operators cannot perform certain functions such as deleting test results from the instrument database. These and other configuration options are entered using HEMOCHRON *Configuration Manager* Software on a personal computer.

Definitions and Terms

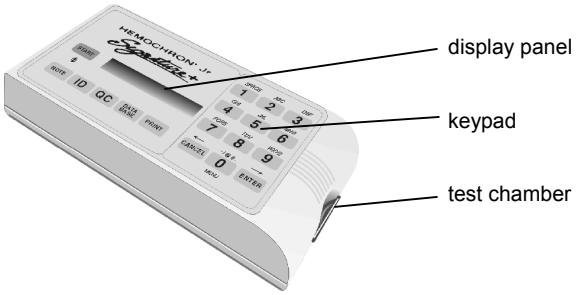
The following acronyms and abbreviations are used in this manual, instrument screens, and printouts:

ACT	Activated Clotting Time
APTT	Activated Partial Thromboplastin Time
DB	Database
EQC	Electronic System Verification Cartridge (EQC)
idms	Integrated Data Management System
INR	International Normalized Ratio
LQC	Liquid Quality Control
OID	Operator Identification Number
PID	Patient Identification Number
PIN	Operator Personal Identification Number
POCC	Point of Care Coordinator
PT	Prothrombin Time
QC	Quality Control
TQC	Temperature Verification Cartridge

DESCRIPTION

The HEMOCHRON Jr. *Signature+* instrument is a hand-held device. It contains a **test chamber** which warms a test cuvette to the required temperature, and it performs all operations to measure the clotting time of a whole blood sample after it is placed in the test cuvette and the test is started by the operator.

Operator instructions are shown on the **display panel**, and the operator enters commands and information using the **keypad**. When the test is completed, the results are shown on the display panel and stored in system memory for printing or downloading.

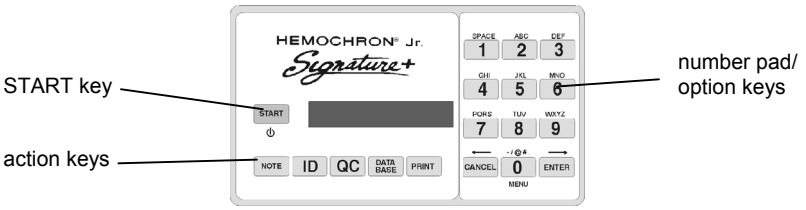


Keypad

The front panel contains a keypad with various action keys as well as a number pad. The operator uses the keypad to select a command or enter information.

Action keys display a menu of commands according to the label on the key. For example, the **PRINT** key displays printing commands. **Number pad** (or **option**) keys are used to enter numerals for IDs or selection of commands.

Note: *The* ***0*** *(zero) key is used as both a numeral key and an action key.*



Key	Purpose
START	Start the instrument or turn off instrument. Initiate a test after the test cuvette has reached 37 ±1.0 °C and the sample is added.
NOTE	Select a laboratory-defined note (from nine choices programmed via HEMOCHRON *Configuration Manager*) for entry into the record for the current test.
ID	Enter a Patient ID or Operator ID.
QC	Specify that the QC sample being run is a normal (Level 1) or abnormal (Level 2) control. (For QC Lockouts) Display the length of time remaining before Quality Control testing for a particular test must be successfully completed.
DATABASE	Display the number of patient or QC test results that are currently stored in the instrument and the number of additional test results that can be stored. Display results of the last 100 patient or QC tests. Delete patient or QC records.
PRINT	Print results on an external printer for the last test result, patient database, quality control database, or all test results for a specified patient. Test the printer. Enter a customized header. Print instrument system information.
0 (zero key)	(When no tests are running and no menu is active) Display the main menu.
0 through **9**	Select a menu option. Enter numeric information (e.g., a Patient ID, an Operator ID, a time, or a date).
CANCEL	Cancel an operation and return to the previous state.
ENTER	Accept a numeric entry (e.g., a Patient ID, an Operator ID, a time, or a date).

Display Panel

The instrument communicates with the operator by means of the display panel. For example, ADD SAMPLE and PRESS START are alternately displayed after a test cuvette reaches 37 ±1.0 °C:

Add Sample

The display is illuminated to enhance visibility in low light conditions. To conserve power during battery operation, the display is not illuminated when the test well is empty or when a test is running. The display is momentarily illuminated after a key is pressed or when results of a completed test are displayed. While a test is running, the display can be momentarily illuminated by pressing the **CANCEL** or **ENTER** key or any numeric key.

Menus

The action keys display the various commands for operating and configuring the system. Display a menu by pressing the corresponding action key. For example, press the **PRINT** key to display the print menu title:

PRINT MENU

Display each command on a menu by pressing the action key again (or the zero key). For example, if the PRINT menu is displayed, press the **PRINT** key or **0** repeatedly to scroll through the commands on the PRINT menu:

1–Print Last	3–Print QC DB	6–Enter Header
2–Print PAT DB	4–Print by PID	7–Print System
	5–Print Check	

Execute a command by pressing the **ENTER** key while the command is displayed or by pressing the numeric key for that option when the menu is displayed. For example, press **3** while PRINT MENU (or any command on the PRINT menu) is displayed to print the QC database:

Printing QC DB

The commands displayed after successive keystrokes on each action key are summarized below:

Menu	Action Key	Commands	
Note	**NOTE**	(First)	Enter Note#
		(Successive)	Predefined Notes **1** through **9**
ID SELECTS	**ID**	(First)	ID SELECTS
		(Successive)	1–Enter PID
			2–Enter OID
QC SELECTS	**QC**	(First)	QC SELECTS
		(Successive)	1–QC Normal
			2–QC Abnormal
			3–Patient Result
			4–QC Status
DB SELECTS	**DATA BASE**	(First)	DB SELECTS
		(Successive)	1–Pat DB Totals
			2–QC DB Totals
			3–Pat DB Erase
			4–QC DB Erase
			5–Display Pat DB
			6–Display QC DB

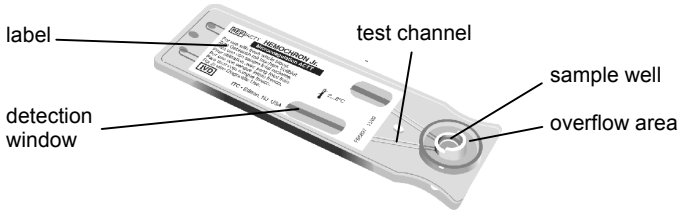
Menu	Action Key	Commands	
PRINT MENU	**PRINT**	(First)	PRINT MENU
		(Successive)	1–Print Last
			2–Print Pat DB
			3–Print QC DB
			4–Print by PID
			5–Print Check
			6–Enter Header
			7–Print System
MAIN MENU	**0 (Zero)**	(First)	MAIN MENU
		(Successive)	1–Power Level
			2–System Time
			3–System Date
			4–Shutdown
			5–System Info

Instrument Shutdown

To shutdown the HEMOCHRON Jr. *Signature+*, press **0** (zero) to display the main menu and then press **4**. Or, press and hold down the **START** key for four seconds. If not in use, the instrument will automatically shutdown after five minutes.

Test Cuvettes

Tests are performed with single-use disposable HEMOCHRON Jr. test cuvettes. Each test cuvette contains a **label**, a **sample well**, a **test channel** containing reagents, an enclosed **waste reservoir**, and optical **detection windows**.



The cuvette label is human- and instrument-readable. The current test is automatically read by the instrument and displayed for confirmation when the operator inserts the cuvette into the test chamber. After the cuvette has warmed to 37 ±1.0 °C, ADD SAMPLE and PRESS START are displayed by the instrument, alerting the operator to place a drop of blood in the sample well and begin the test by pressing the **START** key.

***Note**: Refer to the package insert accompanying the HEMOCHRON Jr. test cuvettes for storage and handling instructions.*

Features

The HEMOCHRON Jr. *Signature+* has a number of performance and convenience features. These are summarized below:

- the system is portable for bedside use
- fresh whole blood or citrated whole blood can be used (assay dependent)
- only one drop of blood is required
- results are available in minutes
- results are displayed appropriately as whole blood, plasma equivalent, Celite equivalent seconds, or INR
- test type is automatically read from the cuvette
- test results are automatically stamped with date and time
- results from 400 patient tests and 400 QC tests can be stored
- stored results can be printed and/or downloaded to a personal computer
- stored results can be searched by Patient ID
- instrument self checks are automatically performed
- Electronic Quality Control (EQC) cuvettes are used to check instrument operation at two levels
- a Temperature Verification cuvette can be additionally used to check test chamber temperature
- the display is illuminated for viewing in low light
- the user is alerted when the battery is low
- an optional printer can be connected
- the system can be customized using a personal computer and HEMOCHRON *Configuration Manager* software
- User Notes can be entered to add additional information to the test results
- Patient/QC test reports can be created using a personal computer and ITC data management software programs

ATTENTION LABEL

An attention label on the rear of the HEMOCHRON Jr. *Signature+* instrument alerts users to accompanying documentation:

Before using the HEMOCHRON Jr. *Signature+* instrument, it is essential that the contents of this *Operator's Manual* are read and understood by the operator.

Handle and open the container with care.

Instrument Lockouts

The instrument can be configured to allow use only by authorized operators and/or to allow use only if specified QC has been performed. If one or more of these lockouts is enabled, processing of the lockout(s) occurs before any other instrument functions.

Prewarming

If the lockout checks are passed, a cuvette is automatically prewarmed to 37 °C ±1.0 °C when it is placed in the test chamber. The instrument will sound one short beep when pre-warming is complete.

Automatic Interrupt

To ensure accurate test results, incubation of a cuvette stops automatically if **START** is not pressed within five minutes after ADD SAMPLE and PRESS START are displayed.

Test Termination

A test terminates and operation of the test chamber automatically shuts off if clot formation is not detected within a test-specific, preset maximum time.

> ***Note**: Results that are greater than the time noted in the package insert for a test are beyond the sensitivity range of the test. They should be repeated immediately and, if confirmed, reported as greater than the maximum sensitivity range.*

SPECIFICATIONS

Specifications for the HEMOCHRON Jr. *Signature+* Whole Blood Microcoagulation System are listed below.

Dimensions and Weight

Depth	9 cm (3.5 in)
Width	19 cm (7.5 in)
Height	5 cm (2.0 in)
Weight	0.60 kg (1.3 lbs)

Performance

Test Precision	≤ 10% C.V.

Operation

Test Chamber	1
Timing Range	0 second to 1005 seconds
Incubation Temperature	37 °C ±1.0 °C
Incubation Warm-Up Time	30 seconds to 90 seconds
Full-Charge Operating Time	2 to 3 hours (minimum)
Battery Life	500 recharges
Battery Type	Nickel Metal Hydride
Throughput (Full Charge)	49 test cycles (at 150 sec per test)
	17 test cycles (> 500 sec per test)
Operating Environment	15 °C to 30 °C

AC/DC Power Module

USA/Canada

Input Power	120 VAC, 60 Hz, 35 VA
Output Power	9.0 VDC, 1.38 Amps maximum

Europe

Input Power	230 VAC, 50 Hz, 30 VA
Output Power	9.0 VDC, 1.15 Amps maximum

Japan

Input Power	100 VAC, 50/60 Hz, 40 VA
Output Power	9.0 VDC, 1.3 Amps maximum

Calibration

The *Signature+* instrument is calibrated at the manufacturer facility to test and verify all functions. The instrument is also self-calibrating, as all instrument functions are continuously monitored and verified by the instrument software when a test is performed. The instrument does not require additional calibration by the user.

PREPARING THE INSTRUMENT

Unpacking and Inspection

***Note**: Inspect each component for damage when unpacking. If damage is observed, contact your shipper or service representative immediately.*

1. Remove any protective packaging that may be present around the instrument.
2. Examine the packaging material to be sure that the power supply, connecting cables or other components have been removed. The materials that are provided are listed below.

   ***Note**: Do not discard the packaging material.*

Materials Provided

Article	Quantity
HEMOCHRON Jr. *Signature+* Microcoagulation Instrument	1
PC Cable (ITC Part No. HJ7405; see *Connecting a Computer or Printer* on the following page)	1
AC/DC Power Module (see note below)	1
USA/Canada (ITC Part No. HJ7353)	
Europe (ITC Part No. HJ7436)	
Japan (ITC Part No. HJ7409)	
Electronic System Verification Cartridges (EQC)	2
Temperature Verification Cartridge (TQC)	1
Operator's Manual	1
HEMOCHRON *Configuration Manager* CD	1

Materials Required, But Not Provided

Article	Quantity
HEMOCHRON Jr. Test Cuvettes	As Needed
HEMOCHRON Jr. Quality Control Products	As Needed

Optional Materials

Article	Quantity
HEMOCHRON Jr. PKIT (Printer Kit)	1
HEMOCHRON Jr. PCKIT (Personal Computer Interface Cable)	1
HEMOCHRON Jr. CBL-SIG (Serial Printer Interface Cable)	1
HEMOCHRON *ReportMaker* 4.0 or higher CD (Data Management Software)	1
idms v7.1 or higher (Integrated Data Management System)	1

***Note:** The AC/DC Power Module that is provided is the one that is appropriate for the country to which the HEMOCHRON Jr. Signature+ instrument is being shipped. An AC power cord is not provided with the European AC/DC Power Module (ITC Part No. HJ7436).*

Charging the Battery

The battery of the system should be charged before the system is used.

1. Plug the AC/DC Power Module into an electrical service outlet.

   ***Caution**: Ensure that the input voltage requirements of the AC/DC Power Module match the voltage used in the laboratory.*
2. Connect the AC/DC Power Module cord to the power connector on the side of the instrument.
3. Allow the battery to charge for at least 16 hours.

   ***Note**: The AC/DC Power Module can remain connected all the time.*

Battery Warning

The message CHARGE BATTERY is displayed intermittently when the remaining battery power is below a predetermined level. The message BATTERY DEAD is displayed when the battery is completely discharged and cannot be used to run additional tests. The AC/DC Power Module must be used for additional tests until the battery is recharged.

Checking the Battery

1. Press **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu:

MAIN MENU

3. Press **1**. The battery status is displayed:

BAT-OK 9.0V

   Note: *Battery status is displayed as* ***OK****,* ***LOW****, or* ***Weak****.*
4. Press **CANCEL** to return to normal operation.

Setting the System Time and Date:

The time and date a test is run is saved with the test results. The system time and date can be reset by the operator unless the system is in a lockout condition or the time and date are permanently locked (see the *Configuration Manager* section on page 26).

Note*: If the unit has been off for an extended period of time or the battery is very weak, the operator will be prompted to enter or verify that the time and date are correct.*

To Set the System Time:

1. Press **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu:

MAIN MENU

3. Press **2** to display the time:

TIME: 8:26

4. Enter the new time using the numeric keys.

   Note*: Use the 24-hour format (i.e., enter 15:30 for 3:30 pm). The leading zero is required for single digit times (i.e., enter 06:30 for 6:30 am).*
5. Press **ENTER**. DATA STORED is displayed and the entry is saved.
6. Press **CANCEL** to return to normal operation.

To Set the System Date:

1. Press **START** to turn on the instrument.
2. Press **0** (zero) to display the main menu:

MAIN MENU

3. Press **3** to display the date:

DATE:

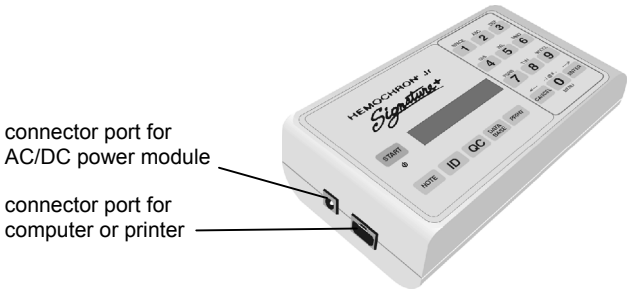
4. Type the new date using the numeric keys.

   Note*: Use the European (i.e.,* ***DD****/****MM****/****YYYY****) or the US (i.e.,* ***MM****/****DD****/****YYYY****) date format. The leading zero is required for single digit dates (i.e., enter 06/01/2004 for June 1, 2004).*
5. Press **ENTER**. DATA STORED is displayed and the entry is saved.
6. Press **CANCEL** to return to normal operation.

   Note*: The main menu cannot be accessed if a cuvette or EQC/TQC cartridge is in the test well. If a cuvette or EQC/TQC cartridge is used to turn on the instrument, it must be removed to access the main menu.*

Connecting a Computer or Printer

An IBM-compatible laboratory computer or a serial printer (Seiko DPU-414 is recommended) can be used with the system. The connector port for these devices is located at the side of the instrument.



To Connect a Printer:

1. Obtain a printer interface cable.

   ***Note**: The printer interface cable is included with the optional HEMOCHRON Jr. PKIT (Printer Kit) only. A separate CBL-SIG (Serial Printer Interface Cable) can be obtained from ITC, or a cable can be prepared as outlined below. If a printer is connected, the serial printer communication parameters must be set to 9600 baud with no parity, 8 data bits and 1 stopbit using XON/XOFF 3-wire software protocol. For additional information on printer configuration, contact ITC Technical Service at **(800) 631-5945** or **(732) 548-5700**, or by e-mail at techservices@itcmed.com.*
2. Connect one end of the cable to the connector port on the side of the instrument.
3. Connect the other end of the printer cable to the printer.

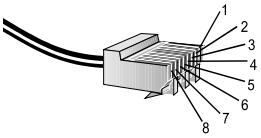
To Connect a Personal Computer:

1. Obtain a computer interface cable.

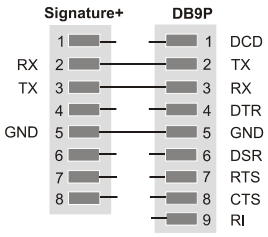
   ***Note:** The computer interface cable is included with the instrument. A replacement PCKIT (Personal Computer Interface Cable) can be obtained from ITC, or a cable can be prepared as outlined below. Contact ITC Technical Service for instructions on setting up the personal computer.*
2. Connect one end of the cable to the connector port on the side of the instrument.
3. Connect the other end of the cable to an unused serial communication port on the computer.

Preparing a Printer or Computer Interface Cable

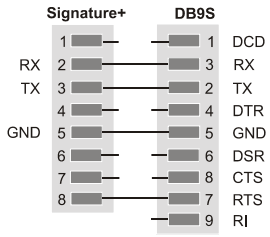
Cabling and connectors can be purchased locally at an electronics store. Use a 6-wire or 8-wire RJ45 to RJ45 modular straight through connecting cable (no longer than 25 feet) plus an RJ45 to DB9 adapter. Numbering of the pins on the RJ45 connectors is shown below:



The cable configurations used for connecting a serial printer or a computer are shown below:



Connecting the instrument to the Seiko DPU-414 printer with a DB9S connector



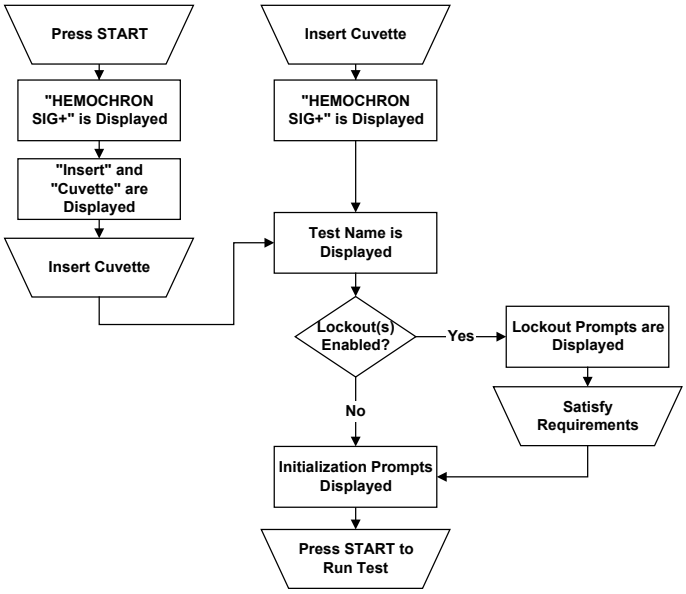
Connecting the instrument to any personal computer with a DB9P connector

STARTING THE INSTRUMENT

Start the instrument by pressing and holding down the **START** key or by inserting a cuvette:

***Note**: Insert the cuvette with the label facing up. Push the cuvette all the way in until it stops. Allow cuvettes to reach room temperature (15 to 30 °C) before opening the pouch. This may take up to 60 minutes. Consult the cuvette package insert for additional information concerning cuvette storage and handling.*

The prompts that are displayed after the instrument is started depend upon whether the **START** key or a cuvette is used and whether or not lockouts are enabled (see the *Configuration Manager* section on page 26):



When a test cuvette (eg. PT) is inserted to turn on the instrument, the following prompts are displayed:

1) HEMOCHRON Sig+ 3) Priming Pump

2) Test . . . . . PT 4) WARMING……... (scrolls right)

***Note**: The test name for the inserted cuvette is displayed after **Test.....** . Check the display for fault messages while the cuvette is warming. Refer to the Troubleshooting section for the procedure to resolve a fault message.*

When the cuvette reaches 37 °C ±1.0 °C, the instrument will beep and alternately display:

Add Sample . . . . . and . . . . . Press Start

The sample can now be added. After the sample is added, press **START** to run the test.

RUNNING A TEST

Samples are designated as patient samples by default. If a control is being run, the sample type must be changed from **patient sample** to **QC Normal** or **QC Abnormal**. If a patient sample is being run, this step is unnecessary.

***Important**: Failure to select **QC Normal** or **QC Abnormal** for a control sample will result in storage of the control results as patient results in the patient database.*

1. Select **QC** to display the QC SELECTS menu:

   QC SELECTS

   ***Note:** To enter QC SELECTS, a cuvette must be inserted into the instrument.*

2. Press **1** to designate the sample as a normal control:

   QC Normal

   Or press **2** to designate the sample as an abnormal control:

   QC Abnormal

   ***Note:** Once the QC SELECTS menu is displayed, the sample type can be selected by pressing **QC** repeatedly until the desired sample type is displayed or by pressing the numeric key corresponding to the desired sample type. The sample type can be designated either before, during, or after the test is run, while the test cuvette is still inserted in the instrument (unless QC lockout features are enabled). Once **QC** is selected, repressing the **QC** key will briefly display the QC level and assay being run.*

   To exit the QC menu, press and hold the CANCEL Key for three seconds.

   Important: Once a QC type is selected, it cannot be changed.

   ***Note**: If any error messages appear on the instrument screen, do not change any previous patient/QC tags. Remove cuvette and repeat test using a new cuvette.*

A numeric Patient ID (PID) and/or Operator ID (OID) can be entered for each test. The IDs will be stored with the results for the test. Entry of a PID and/or OID is optional unless specified otherwise (see the *Configuration Manager* section on page 26). When entering an optional PID or OID, any ID (up to nine characters) other than **0** (zero) can be entered.

To Enter an Optional Patient ID:

1. Select **ID** to display the ID SELECTS menu:

   ID SELECTS

   Note: *To enter ID SELECTS, a cuvette must be inserted into the instrument.*

2. Press **1** to enter a numeric PID.

   PID= _. . . . . .

3. Type the PID using the numeric keys.
4. Press **ENTER**. The entry is confirmed as saved.

   Note: *The PID can be designated (or changed) anytime. Check the PID by pressing **ID** and then pressing **1** to display the entered value. If a PID is not entered for a test, the PID is stored as 0 (zero) in the database.*

To Enter an Optional Operator ID:

1. Select **ID** to display the ID SELECTS menu:

   ID SELECTS

2. Press **2** enter a numeric ID.

   OID= _. . . . . .

3. Type the OID using the numeric keys.
4. Press **ENTER**. The entry is confirmed as saved.

   Note: *The OID can be designated (or changed) anytime. Check the OID by pressing **ID** and then pressing **2** to display the entered value. If an OID is not entered for a test, the OID is stored as **0** (zero) in the database.*

Entering a Mandatory PID, OID, and/or PIN

Entry of a Patient ID (PID), Operator ID (OID), and/or Operator Personal Identification Number (PIN) can be required for completion of a test (see the *Configuration Manager* section on page 26). If entry of one or more of these IDs is required, appropriate prompts for entry of PID, OID and/or PIN are automatically displayed.

To Enter a Mandatory Patient ID:

1. The PID prompt is automatically displayed:

   PID= _. . . . . .

   Note: *When PID=… is displayed, pressing the **QC** button will allow a QC test to be performed without fulfilling the PID requirement.*

2. Type the PID using the numeric keys.
3. Press **ENTER**. If an acceptable PID is entered, operation of the instrument continues:

   Priming Pump

   Note: *An acceptable PID is any number other than zero (**0**). The number of digits to be entered for PID (from **3** to **9**, or **0** for any number of digits up to **9**) may be designated via Configuration Manager. Selecting 3 to 9 digits requires that the operator enter exactly that length. Check the PID by pressing **ID** and then pressing **1** to display the entered value.*

To Enter a Mandatory Operator ID:

1. The OID prompt is automatically displayed:

   OID= _. . . . . .

2. Type the OID using the numeric keys.
3. Press **ENTER**. If an acceptable OID is entered, operation of the instrument continues:

   Priming Pump

   Note: *If entry of any OID is specified, an acceptable OID is any number (up to 9 digits) other than zero (**0**). If entry of a valid OID is specified, an acceptable OID is any number contained in the Operator Table (see page 36).*

   *Check the OID by pressing **ID** and then pressing **2** to display the entered value.*

4. If an unacceptable OID is entered, ID IS NOT VALID is displayed followed by the OID prompt. Operation of the instrument will not continue until an acceptable OID is entered.

To Enter a Mandatory Operator PIN:

1. The PIN prompt is automatically displayed:

   PIN= _. . . . . .

2. Type the Operator PIN using the numeric keys.

   Note: *The Operator PIN will be displayed as ** on the display panel. The corresponding OID will be stored and printed with results.*

3. Press **ENTER**. If an acceptable PIN is entered, operation of the instrument continues:

   Priming Pump

   Note: *An acceptable PIN is any number contained in the Operator Table.*

4. If an unacceptable PIN is entered, ID IS NOT VALID is displayed followed by the PIN prompt. Operation of the instrument will not continue until an acceptable PIN is entered.

Prompts for Mandatory QC Tests

Electronic quality control (EQC) tests and/or liquid quality control (LQC) tests can also be required to be run at specified intervals (see the *Configuration Manager* section on page 26). When it is time for a required QC test to be run, the required QC test must be successfully completed before the specific patient test(s) can be run. If EQC is required, no patient tests can be run until successful completion of EQC.

***Note**: A specified limited number of additional tests (**911 exceptions**) can be run after a mandatory QC interval has been reached. Consult the Configuration Manager section for details.*

To Run a Mandatory QC Test:

1. The prompt for the required QC test is automatically displayed:

   1-QN 2-QA

2. Enter mandatory ID or PIN information (if prompted). If acceptable information is entered, operation of the instrument continues:

   Priming Pump

3. Run the QC test according to the displayed prompts. If the results for the QC test are acceptable, affected patient tests can now be run.

Adding a Note

Up to two operator-selectable notes can be added to the record for each test and will be printed with the final record. The notes are selected from a menu of nine available notes.

***Note**: Consult the Configuration Manager section for the procedure to add a new user-selectable note to the Note Table.*

1. Press **NOTE**:

   Enter Note#=

2. Type the number (**1** through **9**) corresponding to the note that is to be entered or press the NOTE key repeatedly until the desired note is displayed. For example:

   USER TRAINING

   ***Note:** "NOTE NOT USED" is displayed if a note is not defined for that note number.*

3. Press **ENTER**. The number for the selected note is displayed:

   Enter Note#= 6,0

   ***Note:** The number corresponding to the first note is displayed before the comma. The **0** (zero) character after the comma indicates that a second note has not yet been defined.*

4. (If needed) Type the numeral corresponding to a second note and press **ENTER**. The number for the second note is displayed:

   Enter Note#= 2,6

   ***Note:** If a third note is entered, the first note (Note **6** in this example) is cancelled. Currently entered notes can be cancelled by entering **0** (zero) for both notes.*

5. Press **CANCEL** to return to normal operation.

Specimen Collection

Collect blood specimens according to NCCLS document H21-2, entitled *Collection, Transport and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays*.

***Important**: Collect blood specimens in a manner that prevents contamination with tissue thromboplastin, indwelling intravenous (I.V.) solutions, or alcohol cleansing solution. Discard samples that are not properly collected or contain visible clots or debris.*

Use a 23 gauge or larger needle if a syringe is used for blood collection. If a sample is expelled through the same needle, do it slowly to prevent hemolysis.

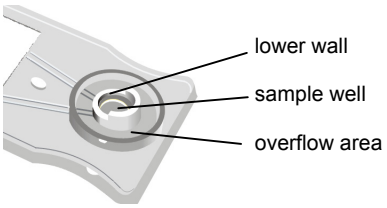
Consult the cuvette package insert for additional information concerning specimen collection and storage.

Starting the Test

After initialization is completed the instrument beeps once, signaling the instrument is ready for the sample. ADD SAMPLE and PRESS START are displayed, and the blood sample can be placed into the cuvette and the test started.

***Note**: START TIMED OUT is displayed if the test is not started within five minutes. If this occurs, repeat the test using a new cuvette.*

1. Place a drop of blood into the sample well of the cuvette:



***Note**: Fill the sample well from the bottom up. Add enough blood so that the lower wall of the center sample well is completely filled. If the meniscus of the blood sample extends above the lower wall, push the excess blood into the overflow area. A transfer needle can be used to transfer blood.*

2. Press the **START** key. The elapsed time (in seconds) is displayed until the sample clots.

   ***Note**: SAMPLE TOO SMALL, SAMPLE TOO LARGE, or SAMPLE NOT SEEN is displayed if an incorrect amount of sample was added. Repeat the test using a new cuvette.*

3. When a clot is detected, the instrument beeps once. Final results of the test are calculated and displayed.

   ***Note**: The whole blood clotting times are converted to plasma equivalent values (for APTT and APTT Citrate), or plasma equivalent values and International Normalized Ratio (for PT and PT Citrate). Press the **START** key to display the whole blood clotting times (for three seconds). Celite equivalent values are displayed for ACT+ and ACT-LR.*

4. Remove the cuvette and discard it.

   ***Note**: Results are saved in the database and printed if a printer is connected. The date and time of the test, the PID, OID, notes (if entered), and error message (if a fault is detected for the test or sample) are printed with the test result.*

QUALITY CONTROL (QC)

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recommends that medical and laboratory instrumentation be enrolled in a quality assurance program adequate in maintaining accurate and reliable performance of the equipment. Complete records of such quality control must be kept.

Routine quality control testing should be part of a comprehensive quality assurance program. Quality control testing of the HEMOCHRON Jr. *Signature+* consists of the following operations:

- Testing system performance using Electronic System Verification Cartridges at two levels every eight hours of operation.
- Testing cuvettes in accordance with the Package Insert for each assay using two levels of liquid controls.

Self-Check

The HEMOCHRON Jr. *Signature+* instrument performs a "self-check" every time it is activated and a test is performed. When a test is initiated by inserting a cuvette, system checks are automatically performed and include:

- Verification of adequate battery power to complete a full test.
- Verification of the test type on the screen display to insure that the LEDs used for identifying the test are functioning properly.
- Verification that the cuvette temperature is warmed to 37± 1.0 ºC. If this temperature is not achieved or is exceeded, an appropriate error message will be displayed and testing is prohibited.
- Verification that the sample is present and is of sufficient size to run test. This insures that the pumps and sample sensing LEDs are functioning properly and that the cuvette is adequately sealed. If these instrument and sample parameters are not appropriate, the test is terminated and an error message displayed.
- Verification that the internal timers function correctly for each test. If the system timer and assay timer disagree, a real-time clock error message is displayed and the test result is not reported.

QC of Instrument Performance

The instrument should be tested at two levels once every eight hours of operation. Electronic quality control cartridges (EQC Cartridges) can be used to provide a two-level electronic verification of instrument performance, or liquid quality control products can be used.

QC Using EQC Cartridges:

1. Insert the corresponding EQC Cartridge into the instrument. Enter an Operator ID (optional) for the test. The instrument will beep once and display:

   E-QC ……..TEST

   ***Note**: System verification checks are performed during this process. If a fault is encountered, the instrument will beep several times and display the error message. Refer to the Troubleshooting section for the procedure to resolve an error message.*
2. After a short interval, the instrument will beep once and alternately display:

   Press E-QC …….. and …….. Start Now
3. Press the **Start** button on the EQC Cartridge. The instrument displays the elapsed time (in seconds) until the EQC Cartridge simulates an endpoint.
4. When the EQC Cartridge simulates an endpoint, the instrument beeps twice. Final results of the test, along with a PASS or FAIL designation, are displayed and saved in the database when the cartridge is removed.

   ***Note**: If a printer is connected, the results are printed when the EQC Cartridge is removed.*
5. Compare the displayed time with the acceptable range for the EQC Cartridge and remove the EQC Cartridge.
6. Repeat the procedure using the other EQC Cartridge.

QC Using Liquid Quality Control Products:

1. Obtain the liquid quality control products.

   ***Note**: HEMOCHRON Jr. Quality Controls are recommended. Refer to the package insert for the liquid quality control products for storage and handling information.*

2. Select QC NORMAL (or QC ABNORMAL) and enter an Operator ID (optional) for the test.

   ***Important**: LQC results will be stored in the patient database if QC NORMAL or QC ABNORMAL is not selected for the test.*

3. Obtain a cuvette for the test to be validated and insert it into the instrument.
4. When ADD SAMPLE and PRESS START are displayed, add the appropriate liquid control sample and run the test in the same manner as for a patient sample.

   ***Note**: If any error messages appear on the instrument screen, do not change any previous patient/QC tags. Remove cuvette and repeat test using a new cuvette.*

QC of Cuvettes

Cuvette validation is carried out using the appropriate HEMOCHRON Quality Control Product kit and the test procedure provided.

Acceptable performance ranges for the HEMOCHRON Jr. cuvettes are included with each HEMOCHRON QC product kit. The cause of out-of-range results is likely attributable to test technique, control material, cuvette and/or the instrument.

Additional Method to Verify Instrument Temperature

A Quality Control temperature evaluation of the HEMOCHRON Jr. *Signature+* instrument is performed automatically each time a test is run (see the Self-Check section on page 20). However, for purposes of your QC program, it may be preferred to additionally perform a temperature QC evaluation using the ITC Temperature Verification Cartridge to verify that a temperature of 37 °C ±1.0 °C is maintained. The Temperature Verification Cartridge can be obtained from ITC.

Checking QC Intervals

If EQC tests and/or LQC tests are required to be run at specified intervals, the amount of time remaining before QC must be run on each test can be checked.

To Check QC Intervals:

***Note**: If a cuvette is **not** inserted in the instrument, pressing QC will immediately display QC Status.*

1. With a cuvette inserted, press **QC** to display the QC SELECTS menu:

   QC SELECTS

2. Press **4**. The time before QC must be run on the first test (e.g., APTT) is displayed:

   APTT-N >1 day

3. Press **QC** to display the time remaining for each of the other tests.

OPERATING PRECAUTIONS

The AC/DC Power Module should be plugged into a standard AC outlet to charge the instrument when it is not in use.

DO NOT remove the AC/DC Power Module from the instrument by pulling on the cord. Although the AC/DC Power Module can be left plugged into an AC outlet when the instrument is unplugged, it is recommended that the AC/DC Power Module be unplugged from the AC outlet when it is not being used to charge the instrument.

DO NOT use cuvettes that are past their marked expiration date or which have been improperly stored.

DO NOT force a cuvette into the instrument. If resistance to insertion is encountered, gently remove the cuvette and examine the cuvette slot. Remove any obstruction before attempting further use of the instrument (see *Service and Maintenance* on page 48).

DO NOT use excessive force in pressing the instrument keys.

DO NOT expose the instrument to extreme temperatures (above 37 °C).

DO NOT drop the instrument.

The HEMOCHRON Jr. *Signature+* instrument should only be used by healthcare professionals trained and certified in the use of the system and operated in accordance with facility policies and procedures.

All biohazard safety guidelines pertaining to the handling and disposal of human blood should be strictly adhered to when collecting and handing blood specimens and when operating the HEMOCHRON Jr. *Signature+* Microcoagulation instrument.

Used HEMOCHRON Jr. test cuvettes should be considered as potentially infectious. They should be handled according to individual institutional policies concerning the disposal of potentially infectious materials.

HEMOCHRON Jr. *Signature+* test results should always be scrutinized in light of a specific patient's condition or anticoagulant therapy. Any test results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional diagnostic tests. Samples with a hematocrit less than 20% or greater than 55% are not recommended, due to an optical density outside the detection level of the HEMOCHRON Jr. *Signature+* Microcoagulation instrument.

> ***CAUTION**: Verify that any third-party connectivity software to be used is compatible with the software version of the HEMOCHRON Signature+ instrument in use. Transferred data will be lost if third-party connectivity software is used with non-compatible versions of HEMOCHRON Signature+ software.*

LIMITATIONS

Test results of the HEMOCHRON Jr. *Signature+* Microcoagulation instrument are affected by poor technique during blood collection and delivery to the sample well. The accuracy of the test is largely dependent upon the quality of the blood specimen, including the blood sample collection and the transfer of blood to the test cuvette. Refer to the individual assay package insert for specific limitations.

RESULTS MANAGEMENT

Up to 400 patient test results and 400 quality control test results can be stored in the instrument. In addition to test results, the date and time of each test, PID, and OID are also stored.

***Note**: PID and/or OID are stored as **0** (zero) if a value is not entered when the test is run. A PID is not required for any QC test.*

To Print Results:

1. Press **PRINT** to display the PRINT menu:

   PRINT

Then perform one of the following procedures:

To Print Results of the Last Test:

1. Press **1**. Results of the last test are printed.

To Print All Results in a Database:

1. Press **2** to print all of the results in the patient database. Or, press **3** to print all of the results in the QC database.

To Print All Results for a Patient:

1. Press **4** to enter a PID:

   PID= _. . . . . .

2. Type the PID using the numeric keys.
3. Press **ENTER**. All results for the specified patient are printed.

To Check Printer Function:

1. Press **5** to output an ASCII character set to an attached printer to verify that the printer port functions properly.

   HEMOCHRON Signature+ Print Test
   !"#$%&'()*+,-./012345678
   9:;<=>?@ABCDEFGHIJKLMNOP
   QRSTUVWXYZ[\] ^ _ `abcdefgh
   ijklmnopqrstuvwxzy{ | }~

To Enter a Custom Header:

1. Press **6**. This feature allows creation of a custom header to appear on the top of each printout. The default header is - - -ITC - - -.
2. Create the custom header using the alphanumeric keypad.

   Press a key once to display the key's numeric value. Press the key once more (within one second) to display the first alpha character mapped to the key. Hold down the key to cycle through the assigned numeric and alpha characters at a one-second interval.

   Release the key (for at least one second) when the selected character is displayed. The character is saved and the cursor advances to the right.

   Use the **CANCEL** key as a left-arrow key and the **ENTER** key as a right-arrow key.
3. When the desired header is displayed, press and hold the ENTER key (for at least one second) to save the header. Press and hold the CANCEL key to return to the ENTER HEADER prompt without saving the new header.

To Print System Information:

1. Press **7** to print the system software version, system serial number, and program parameters.

To Abort Printing of Results:

1. Pressing **CANCEL** for three seconds will abort data transmission to the printer. Any data previously transmitted will complete printing.

***Note**: If an error is encountered with the test or the sample, the error message for the error will be included on the printout. Refer to page 46 for error messages, their cause, and their resolution.*

Other Database Operations

Results of the last 100 tests can be reviewed for both patient and QC results. The total number of test results that are currently stored and the total number of additional test results that can be stored can be displayed. Finally, the results in either the patient database or the quality control database can be erased to make room for additional test results.

***CAUTION**: Results from the oldest test are overwritten if a test is run when the database is full. Therefore, it is important to periodically check, print, archive, and erase the database contents.*

To Perform Other Database Operations:

1. Press **DATABASE** to display the DATABASE menu:

DB SELECTS

Then perform one of the following procedures:

To Display Total Tests and Remaining Tests in the Database:

1. Press **1**. The total number of stored patient records and the number of records that can still be added to the patient database are displayed:

41 Tests/359 Left

Or, press **2**. The total number of stored QC records and the number of records that can still be added to the QC database are displayed:

12 Tests/388 Left

To Delete All Results from a Database:

1. Press **3** to erase the patient database.

   Or, press **4** to erase the QC database.
2. The instrument displays a prompt to confirm deletion of the database:

Sure? 1-YES 2-NO

3. Press **1** to confirm deletion. COMPLETED is displayed for two seconds.

***Note**: Press **2** or **CANCEL** to cancel erasing of the database.*

To Review Results of the Patient Database:

1. Press **5**. The first line of the results for the most current test record is displayed.

01 PAT ACT-LR

2. To review each additional line of the results, press **0** or **8** to scroll up or down through the record.
3. To scroll through additional test records, press **ENTER** (for the next record) or **CANCEL** (for the previous record).

To Review Results of the QC Database:

1. Press **6**. The first line of the results for the most current test record is displayed.

2. To review each additional line of the results, press **0** or **8** to scroll up or down through the record.
3. To scroll through additional test records, press **ENTER** (for the next record) or **CANCEL** (for the previous record).

To Exit Database Operations:

1. Press and hold **CANCEL** for two seconds.

Acronyms for Error Messages

The following table lists the acronyms for Error Messages when viewing stored Patient or QC records:

Acronym	Description	Display Message
ORH	Out of Range High	Out of Range-Hi
ORL	Out of Range Low	Out of Range-Lo
SNS	Sample Not Seen	Sample Not Seen
STS	Sample Too Small	Sample Too Small
STL	Sample Too Large	Sample Too Large
TTO	Temp Timeout	Heater Too Cool
TTH	Temp Too High	Heater Too Hot
SPF	Sample Position Fault	Sample Pos Fault

Downloading QC/Patient Data to Your PC

For information on downloading QC/Patient data to your PC without ITC data management software, contact ITC Technical Service for instructions.

CONFIGURATION MANAGER

HEMOCHRON *Configuration Manager* (HCM) software V1.1 or higher allows the supervisor to configure HEMOCHRON Jr. *Signature+* instruments so they meet the needs of the laboratory. The configuration is performed on a personal computer that is connected to the instrument by means of a computer interface cable.

Refer to the online **Help** in HCM software for additional information.

Personal Computer Requirements

A personal computer with installed HEMOCHRON *Configuration Manager* software is required for configuring a HEMOCHRON Jr. *Signature+*. Instructions for connecting the personal computer to the instrument are provided on page 11.

The personal computer must meet the following minimum requirements:

- For Microsoft Win98, WinME: A Pentium 100 MHz or higher microprocessor and a minimum of 64 megabytes (MB) of random-access memory (RAM).
- For Microsoft WinNT 4.0, Win2000 or WinXP: A Pentium II 400 MHz or higher microprocessor and a minimum of 128 megabytes (MB) of random-access memory (RAM).
- If you are running Windows 2000 or Windows XP, you must have System Administrator or Power User security privileges.
- Hard disk with at least 50 MB of free space.
- VGA 800x600 or higher resolution supported by Microsoft Windows.
- One RS-232 serial port for connecting to an instrument.
- CD-ROM drive.

Loading *Configuration Manager* Software

The Setup program creates HEMOCHRON *Configuration Manager* working directories. It copies programs and configuration files to the working directories and adds the HEMOCHRON *Configuration Manager* (ITC HCM) program icon to the desktop.

1. Start Microsoft Windows.
2. Insert the HEMOCHRON *Configuration Manager* installation CD-ROM in the CD drive.
3. Follow the instructions on the screen.

   ***Note**: The System Configuration dialog box (page 41) is displayed for entry of institution information and the PC COM port that is being used. You will also be prompted to specify a folder for the installation and to specify a folder for the program icon.*
4. A message will be displayed when the software is successfully loaded. After the message is displayed, remove the CD from the computer.
5. Shut down and restart the computer if prompted to do so.

Linking a HEMOCHRON Jr. *Signature+* Instrument

The HEMOCHRON Jr. *Signature+* instrument that is being configured must be linked to HEMOCHRON *Configuration Manager*.

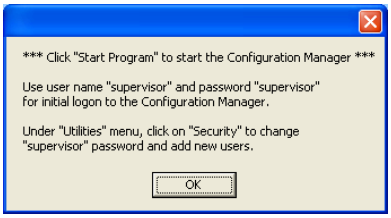
1. Connect the HEMOCHRON Jr. *Signature+* instrument to the personal computer on which HEMOCHRON *Configuration Manager* is installed.

   ***Note**: Refer to page 13 for connection details. A computer interface cable is included with the instrument and CD, or a separate PCKIT (Personal Computer Interface Cable) can be obtained from ITC. Alternatively, the cable can be prepared as outlined on page 13.*
2. Start *Configuration Manager* software (see page 27).
3. If necessary, designate the PC COM port to use.

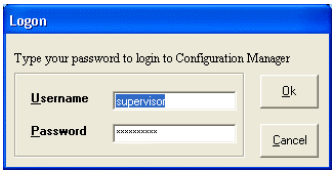
Starting *Configuration Manager*

1. Select the ITC **CM** program icon. The Startup window is displayed:

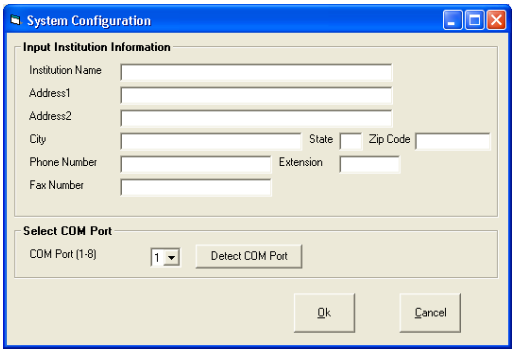
2. When HEMOCHRON *Configuration Manager* software is run for the first time, instructions are displayed to logon using the default user name and password:


*** Click "Start Program" to start the Configuration Manager ***
Use user name "supervisor" and password "supervisor" for initial logon to the Configuration Manager.
Under "Utilities" menu, click on "Security" to change "supervisor" password and add new users.
OK

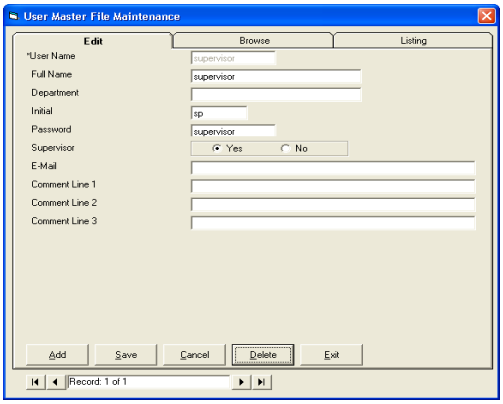
   a. Click **OK** and then click **Start Program**. The Logon dialog box is displayed with the default user name (supervisor) and password (supervisor):



   b. Click **OK**. The System Configuration dialog box is displayed:



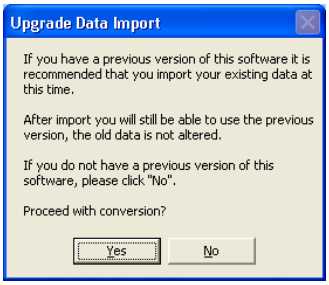
c. Enter information about your institution and COM port used (if needed), then click **OK**. The User Master File Maintenance dialog box is displayed:



d. To change the default user name and password, click **Add** and enter a new user name and password, being sure that the **Yes** button is selected for Supervisor access. Click **Save**, then select the previous record containing the default user name and password and click **Delete**.

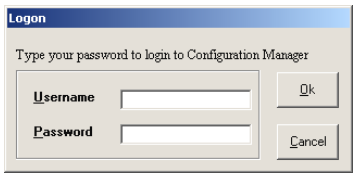
***Note**: The default user name and password should be changed as shown above. All commands are accessible to anyone until then.*

e. Click **Exit**. A prompt to import data from an earlier version of HEMOCHRON *Configuration Manager* software is displayed:


Upgrade Data Import
If you have a previous version of this software it is recommended that you import your existing data at this time.
After import you will still be able to use the previous version, the old data is not altered.
If you do not have a previous version of this software, please click "No".
Proceed with conversion?
Yes
No

f. Click **Yes** or **No** as appropriate.

3. Thereafter, click **Start Program** to display the Logon dialog box:



4. Enter your user name and password.

Menus

Menus for HEMOCHRON *Configuration Manager* functions are displayed at the top of the main window:

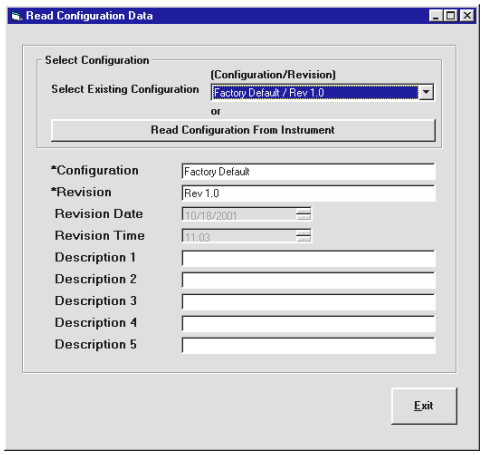
Configuration Manager Main Menu
Configuration Reports Master File Maint. Utilities Exit Help
HEMOCHRON®
Configuration Manager
For Use with the HEMOCHRON Jr. Signature+
Edison, NJ 08820
©2001 International Technidyne Corporation. All rights reserved.
HEMOCHRON is a registered trademark of International Technidyne Corporation.

The use of each menu is described below:

Menu	Purpose
Configuration	Display the Configuration Module dialog box. This dialog box allows the operator to set the various configuration options (see page 31).
Reports	Display and print listings of configuration parameters, instruments, and operators (see page 38).
Master File Maintenance	Display, modify, add, and delete instrument information. Set test type list in *Configuration Manager*.
Utilities	Rebuild and compress the database. Purge selected records. Set up system time check. Display, modify, add, and delete operator information. Convert HEMOCHRON *Configuration Manager* software V1.0 data to V1.1.
Exit	Log off and/or exit the system.
Help	Display the version number of HEMOCHRON *Configuration Manager* software that is installed. Access **Help**.

Selecting a Configuration File

Select **Configuration** in the *Configuration Manager* main menu. The Read Configuration Data dialog box is displayed:



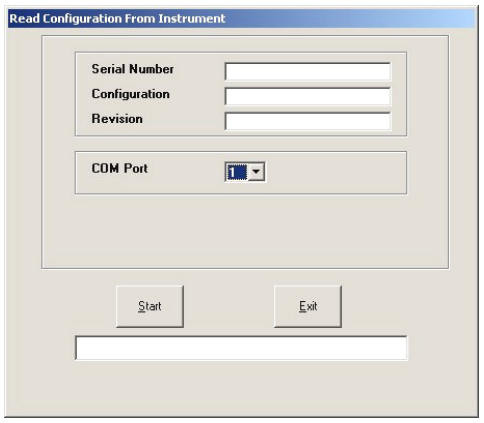
***Note**: HEMOCHRON Configuration Manager uses a Microsoft Windows user interface. Software features are intuitive and easy to learn. Refer to Windows documentation for instructions on navigation, access to commands and **Help**, execution of commands, and shortcuts that can be taken.*

The Select Configuration Data dialog box allows configuration data to be displayed from the connected HEMOCHRON Jr. *Signature+* instrument or from a different configuration file.

***Note**: The default HEMOCHRON Jr. Signature+ settings can be loaded by selecting **Factory Default** for the Select Existing Configuration option. These settings can be modified and saved under a different configuration file name. The Factory Defaults cannot be overwritten or purged from the database.*

To Display Configuration Data from the Connected Instrument:

1. Select **Read Configuration From Instrument**. The name and revision level of the instrument configuration file are displayed in the Read Configuration dialog box:



***Note**: If necessary, designate the COM port by selecting it from the drop-down list.*

2. Click **Start**. The connected HEMOCHRON Jr. *Signature+* instrument is turned on and displays:

3. Verify that the instrument is linked to the PC (see page 26).

   ***Note**: Progress of reading of configuration data is displayed in the status line.*

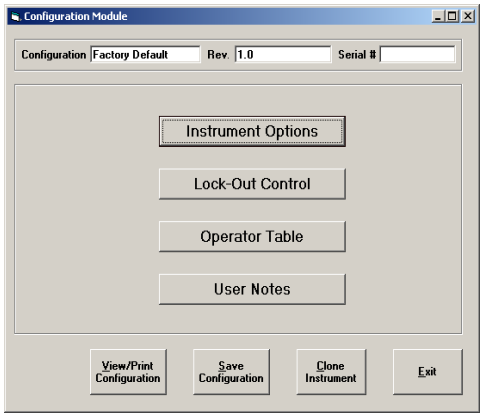
4. When reading of configuration data is completed, click **OK**. The Configuration Module dialog box is displayed.

To Display an Existing Configuration File:

1. Select the file from the Select Existing Configuration drop-down list.
2. Click **OK** when reading of the configuration data is complete. The Configuration Module dialog box is displayed.

Setting Configuration Options

Reading an existing configuration file or reading a configuration file from an instrument will open the Configuration Module dialog box:



Buttons on the dialog box allow the supervisor to display and/or modify configuration information:

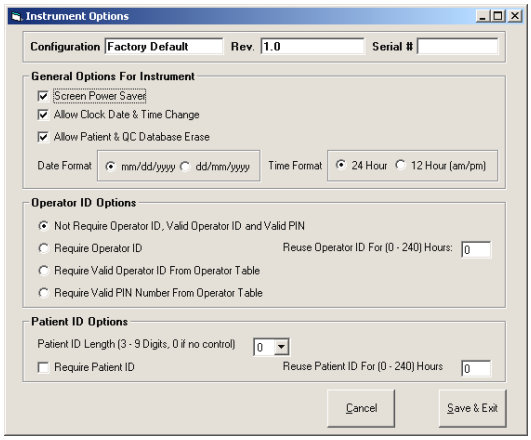
Button	Purpose
Instrument Options	
a. General Options	1. Specify when the display panel is illuminated. 2. Allow operators to change the date or time. 3. Allow operators to erase a database. 4. Specify format for displaying, entering, and reporting date and time.
b. Operator ID Options	1. Require entry of an Operator ID (OID) before a test can be run. 2. Require that the supervisor-specified OID or Personal Identification Number (PIN) must be entered by an operator in order to operate the instrument. 3. Specify that the OID for the previous test is automatically entered for a specified length of time or until a new OID is entered.
c. Patient ID Options	1. Specify the number of digits for a Patient ID (PID). 2. Require entry of a (PID) before a test can be run. 3. Specify that the PID for the previous test is automatically entered for a specified length of time or until a new PID is entered.

Button	Purpose
Lock-Out Control	
a. QC Lockout	1. Specify whether normal and/or abnormal electronic quality control (EQC) testing must be run after a specified time interval has elapsed. 2. For each test type, specify whether normal and/or abnormal liquid quality control (LQC) testing must be run after a specified time interval has elapsed. 3. Prohibit specific test(s) from being performed on the instrument.
b. QC Exceptions	1. If EQC and/or LQC testing must be run after a specified interval, specify the number of additional tests that can be run (the 911 exceptions) after the time interval has elapsed. 2. Specify the number of EQC or LQC test failures that are allowed before the instrument is locked and must be reset by the supervisor.
Operator Table	1. Specify an OID and/or PIN for an operator.
User Notes	1. Specify user-selectable notes that can be entered at the time of a test.

Specifying Instrument Options

Instrument options specify how the instrument communicates with the operator.

1. Select **Instrument Options** from the Configuration Module screen to display the Instrument Options dialog box. Information concerning the configuration file is displayed:



Instrument General Options

1. **Screen Power Saver**: Click the box to enter a check mark to illuminate the display for five seconds when a cuvette is inserted and results are displayed. Leave the check box blank to illuminate the display at all times.
2. **Allow Clock Date & Time Change**: Click the box to enter a check mark to allow the operator to change the date and time on the instrument.
3. **Allow Patient & QC Database Erase**: Click the box to enter a check mark to allow an operator to erase the patient database or the QC database.
4. **Date Format**: Select **mm/dd/yyyy** to display June 1, 2004 as 06/01/2004. Select **dd/mm/yyyy** to display June 1, 2004 as 01/06/2004.
5. **Time Format**: Select **24 Hour** to display 7:15 pm as 19:15. Select **12 Hour** to display 7:15 pm as 7:15 pm.

Operator ID Options

1. **Not Require Operator ID, Valid Operator ID and Valid PIN**: Select if entry of an Operator ID (OID) or PIN is not required when running a test.
2. **Require Operator ID**: Select to require entry of an OID when running a test.
3. **Require Valid Operator ID from Operator Table:** Select to allow operation of the instrument only after an authorized OID is entered.
4. **Require Valid PIN Number from Operator Table:** Select to allow operation of the instrument only after an authorized Operator PIN is entered. All PIN numbers must have a corresponding Operator ID in the Operator Table.

   Note: *Only one of the alternatives listed in steps **1** through **4** can be selected. Authorized OIDs and/or PINs are entered in the Operator Table. Both OID and PIN should be unique for each authorized operator or group in the Operator Table (see page 36).*

5. **Reuse Operator ID**: Enter a value (from **1** to **240** hours) to allow the instrument to use the OID from the previous test as the default entry for the current test.

   Note: *The OID will be entered by default for the specified length of time. The default OID can be changed if needed. If **0** is entered, the OID will not be reused.*

Patient ID Options

1. **Require Patient ID**: Click **Yes** to require entry of a PID when running a patient test.
2. **Patient ID Length**: Select the number of digits (from **3** to **9**, or **0** for any number of digits up to 9) that must be entered for a patient ID.
3. **Reuse Patient ID**: Enter a value (from **1** to **240** hours) to allow the instrument to use the PID from the previous test as the default entry for the current test.

   Note: *The PID will be entered by default for the specified length of time. The default PID can be changed if needed. If **0** is entered, the PID will not be reused.*

Saving the Options

1. Click **Save & Exit** to save the specified options and cancel display of the dialog box.
   Note*: **Cancel** clears all fields without saving any parameters.*

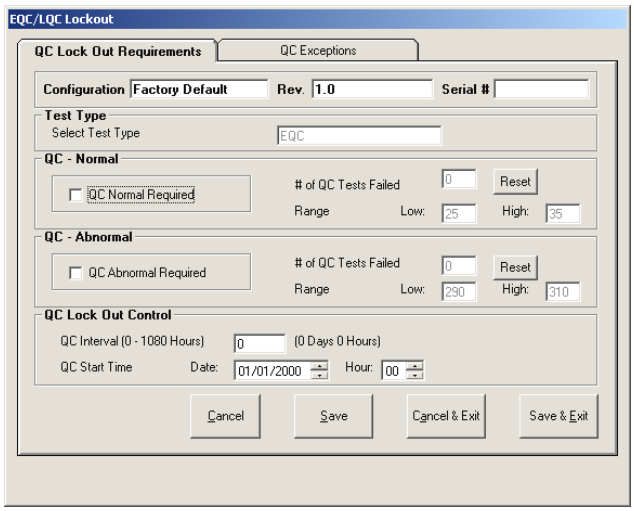
Specifying QC Lockout Parameters

QC lockout parameters specify the maximum length of time that can elapse before liquid quality control (LQC) or electronic quality control (EQC) must be successfully run. When the lockout interval has elapsed and the test cuvette is inserted into the instrument, the user will be prompted to perform the appropriate QC.

If 911 Limits are enabled, the user will be offered the choice to run a patient test. If this option is selected, the instrument displays the number (from **0** to **240**) of remaining tests that can be run (the 911 override) before QC must be performed (see *To Specify QC Exceptions* on page 35). Separate requirements can be specified for the frequency at which EQC and LQC for various tests must be run at normal and abnormal levels.

To Specify Lockout Parameters:

1. Select **Lock-Out Control** from the Configuration Module screen. The EQC/LQC Lockout dialog box is displayed:



2. Select the QC Lock Out Requirements tab (if needed).
3. Use the drop-down arrow to select the **test type** (e.g., PT or EQC) for which QC lockout parameters are to be specified.
4. Enter a check mark in the **QC Normal Required** box to require QC Normal testing to be run at a specified interval.

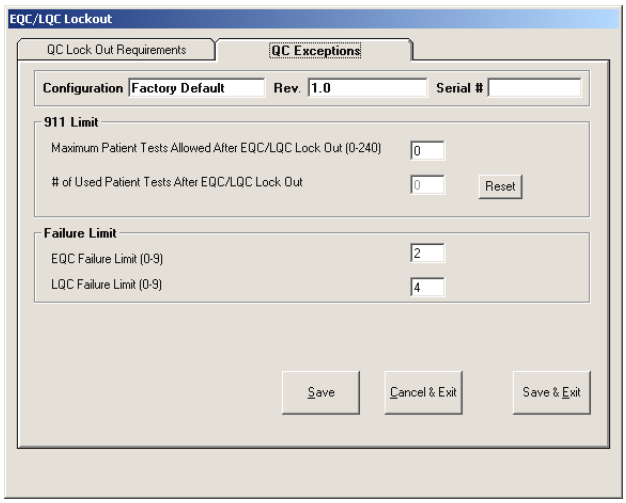
   ***Note**: The number of QC Normal tests that have been run and failed is displayed in the #of QC Tests Failed field. Click **Reset** to reset the number to zero.*
5. (For all tests except EQC) Designate the acceptable range (in seconds) for normal LQC of the specified test by entering a value in the Low and High fields.
6. Enter a check mark in the **QC Abnormal Required** box to require QC Abnormal testing to be run at a specified interval.

   ***Note**: The number of QC Abnormal tests that have been run and failed is displayed in the #of QC Tests Failed field. Click **Reset** to reset the number to zero.*
7. (For all tests except EQC) Designate the acceptable range (in seconds) for Abnormal LQC of the specified test by entering a value in the Low and High fields.
8. (If the QC testing displayed on the tab is required) Enter the maximum length of time (the QC Interval, from 0 to 1080 hours) that can elapse before the QC testing must be successfully run.

   ***Note**: The interval time resets upon successful completion of QC.*
9. (If the QC testing displayed on the tab is required) Enter the date and time when the required QC testing displayed on the tab must be run for the first time. If a start date and time are not entered, the QC testing will be required immediately after Configuration is downloaded to an instrument.
   ***Note**: Subsequent dates and times will be determined automatically from the QC interval.*
10. Repeat steps **3** through **9** as needed for additional QC testing.
11. Click **Save** to save the QC lockout parameters for each test type individually.
    ***Note**: Click **Cancel** to clear the fields without saving the modified parameters. **Save & Exit** saves the EQC/LQC lockout parameters and closes the dialog box.*
12. To disable a particular assay from being run, enter a check mark in the **QC Normal** (or **Abnormal**) **Required** box and then enter **0** for the QC Interval. The message DISALLOWED ASSAY . . . REMOVE CUVETTE displays when a cuvette for that test is inserted.

To Specify QC Exceptions:

1. Select **Lock-Out Control** from the Configuration Module screen. The EQC/LQC Lockout dialog box is displayed.
2. Select the QC Exceptions tab:



911 Limit

1. Enter the maximum number of patient tests (the 911 Limit, from **0** to **240** tests) that can be run after the specified EQC/LQC lockout interval has been reached. When the 911 limit is reached, the instrument cannot be used until reset through *Configuration Manager*.
   ***Note**: The number of patient tests that have already been run against the current 911 override limit is displayed when read from an instrument. Click **Reset** to reset the number to zero.*

Failure Limit

1. EQC Failure Limit: Enter the maximum number of times that a failed EQC test can be rerun before the system will lock (from **0** to **9** tests).
2. LQC Failure Limit: Enter the maximum number of times that a failed LQC test can be rerun before the system will lock (from **0** to **9** tests).
   ***Note**: A failure limit of zero (**0**) will disable the instrument if QC fails.*

Saving the Options

1. Click **Save** to save the QC Exceptions parameters.

   ***Note**: **Cancel** clears all fields without saving any parameters. **Save & Exit** saves the EQC/LQC lockout parameters and closes the dialog box.*

   ***Note**: The number of patient tests that have already been run against the current 911 override limit is not automatically reset when QC is successfully run. Click **Reset** (see above) to reset the number to zero.*

To Unlock an Instrument that has Reached QC Failure Limit or the 911 Limit:

***Note**: The HEMOCHRON Jr. Signature+ must be connected to the Configuration Manager and the instrument configuration information read by clicking on **Read Configuration from Instrument**.*

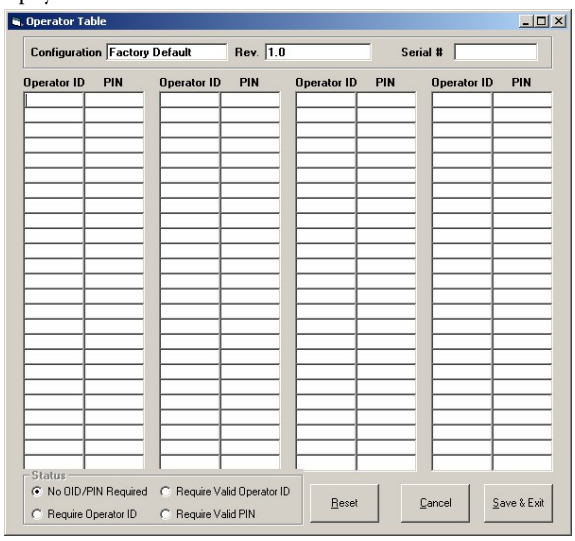
1. Select **Lock-Out Control** from the Configuration Module screen. The EQC/LQC Lockout dialog box is displayed.
2. Use the drop-down arrow to select the test (e.g., PT or EQC) for which QC failed. The failed QC Normal and QC Abnormal tests are displayed in the #of QC Tests Failed fields.
3. Click **Reset** for QC Normal or QC Abnormal to reset the number of failed QC tests to zero for that level.
4. Select the QC Exceptions tab and click **Reset** to reset the number of used patient tests after EQC/LQC Lock-Out.
5. Click **Save & Exit**. The Configuration Module dialog box is displayed (see page 31).

***Note**: The reset configuration must be downloaded to the instrument for these changes to take effect.*

Specifying Operator IDs and/or Personal Identification Numbers

The Operator Table allows the supervisor to specify an Operator ID (OID) and/or Personal Identification Numbers (PINs) for each operator or a group of operators. The supervisor can then specify whether entry of a specified OID or PIN is required before the instrument can be operated.

1. Select **Operator Table** from the Configuration Module screen. The Operator Table dialog box is displayed:



2. Enter a numeric ID for each operator. The ID can be any number (up to 9 digits) other than zero (**0**).
3. Enter a numeric PIN for each operator. The PIN can be any number (up to 9 digits) other than zero (**0**).

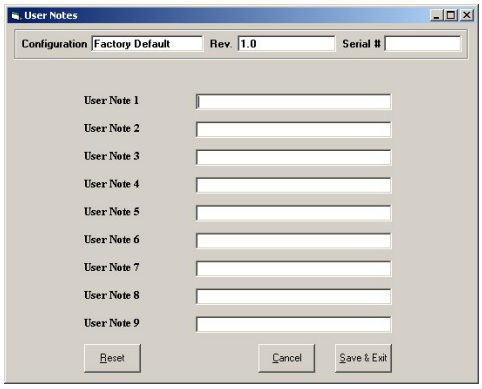
   ***Note**: A unique PIN can be assigned for each authorized operator, or a single OID and PIN can be used to allow operation by any operator that enters the correct code.*
4. The Status box will display the OID/PIN requirements set under Instrument Options. These options are all mutually exclusive.
5. Click **Save & Exit** to save changes to the Operator Table and exit the dialog box.

   ***Note: Cancel** removes the dialog box without saving changes. **Reset** clears all information from the Operator Table.*

Specifying User Notes

Up to nine customized notes can be entered into the **User Notes** menu of an instrument. Up to two of these notes can be selected and appended to a test record by the operator when the test is run.

1. Select **User Notes** from the Configuration Module screen to display the User Notes dialog box. Each field is labeled with the instrument key for that note on the **User Notes** menu:



2. Enter a note (up to 16 characters) for each key.

   Note: *NOTE NOT USED is displayed on the HEMOCHRON Jr. Signature+ instrument if a note is not entered for that note number.*

3. Click **Save & Exit** to save the specified notes and exit the dialog box.

   Note: Reset *clears all fields.* ***Cancel*** *cancels display of the dialog box without saving the modified notes.*

Saving Modified Configuration Data

After configuration data has been modified, the data must be saved to a configuration file prior to downloading to instrument(s) or for future use.

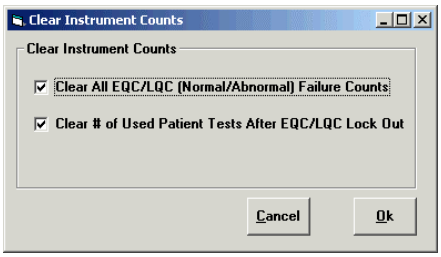
1. Click the **Save Configuration** button.
2. The modified configuration may be saved as a new Configuration filename, or as a pre-existing filename (by selecting a filename from the drop-down list in *Select Existing Configuration File*).

Writing Modified Configuration Data to an Instrument

After configuration data have been modified and saved, the data from the configuration file (or any other saved configuration file) can be downloaded to a HEMOCHRON Jr. *Signature+* instrument.

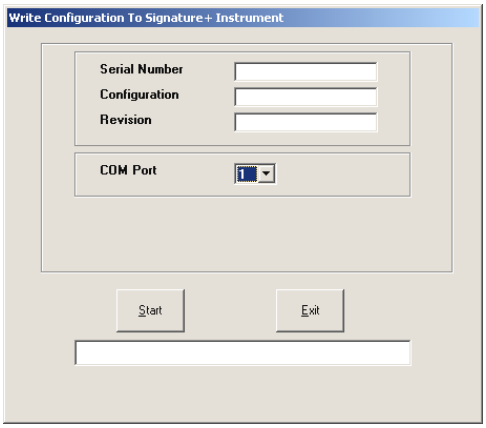
To Write Configuration Data to an Instrument:

1. (If needed) Link the instrument to the PC (see page 26).
2. (If needed) Start HEMOCHRON *Configuration Manager* and select the configuration file that is to be downloaded (see page 30).
3. Select **Clone Signature+ Instrument**. The Clear Instrument Counts dialog box is displayed:


Clear Instrument Counts
Clear Instrument Counts
Clear All EQC/LQC (Normal/Abnormal) Failure Counts
Clear # of Used Patient Tests After EQC/LQC Lock Out
Cancel
Ok

Note: *This allows confirmation that failure counts and 911 use counts will be reset on cloning. If a box is left blank, the corresponding count will not be reset.*

4. Click **OK** to continue.
5. The Write Configuration dialog box is displayed:



6. Click **Start**. Progress information is displayed in the status line.
7. When writing of configuration data is completed, click **Exit**.

Printing Instrument Configuration Data

All of the configuration parameters for an individual instrument or configuration file can be printed.

1. (If needed) Link the instrument to the PC (see page 26).
2. (If needed) Start HEMOCHRON *Configuration Manager* and select the configuration file that is to be downloaded (see page 30) or click on **Read Configuration From Instrument**.
3. The Configuration Module dialog box is displayed.
4. Select **View/Print Configuration**. The configuration report is displayed. Click **Print** using the printer icon.

Displaying and Printing Specific Configuration Reports

Several types of configuration reports can be displayed and printed. The reports provide an audit trail for specific information from all configuration files (or for all instruments) stored in the database:

Specific Report	Description
Instrument Options Listing	Lists the instrument options.
Operator Table Listing	Lists specified OIDs and PINs.
QC Lock-Out Control Listing	Lists selections for EQC/LQC Lock Out.
User Notes Listing	Lists the user notes that have been defined.
Audit Trail Report	Lists the changes made to configuration data files. The report can be sorted by date or user name.

To Prepare a Specific Configuration Report:

1. Select **Reports** in the Configuration Manager main menu.
2. Select the desired report type from the **Reports** menu. The specified information is displayed.
3. Click **Print** to print the report.

MASTER FILE MAINTENANCE

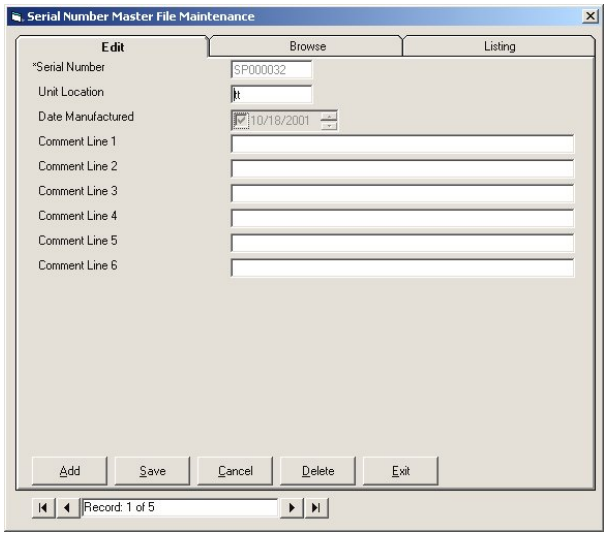
The Master File Maintenance function of HEMOCHRON *Configuration Manager* allows the following:

- Serial Number Master File: Add, modify, or delete a record for a HEMOCHRON Jr. *Signature+* instrument.
- Test Type: Display test name records.

Adding an Instrument

The supervisor can add a new instrument to the table of instrument serial numbers and unit locations.

1. Select **Serial Number** from the **Master File Maintenance** menu. The Serial Number Master File Maintenance dialog box is displayed:



2. Click **Add** to display a blank information form.
3. Enter the serial number, unit location, and comment, if desired. The Date Manufactured is read from the instrument.

   Note: *Entries are not case-sensitive.*
4. Click **Save**. The new instrument record is saved.

Updating an Instrument Record

The supervisor can modify or delete a record for an existing instrument.

1. Select **Serial Number** from the **Master File Maintenance** menu. The Serial Number Master File Maintenance dialog box is displayed listing information for the first instrument record in the database.

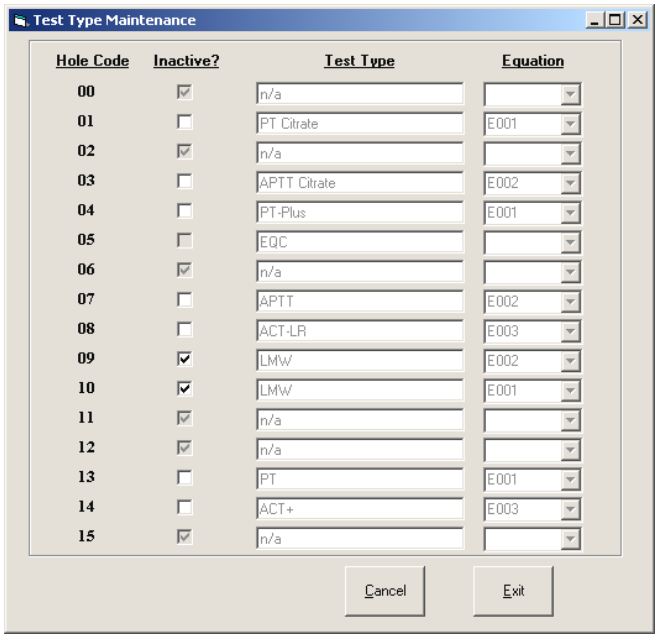
   Note: *The record number and total number of records in the database are displayed at the bottom of the dialog box.*
2. Use the scroll buttons at the bottom of the dialog box to display the record to be updated.
3. Update the information as needed. Click **Delete** to delete the instrument record.

   Note*: Entries are not case-sensitive. The Serial Number field and Date Manufactured field cannot be changed. To change the serial number, delete the record and add a new record for the new serial number.*
4. Click **Save**. The updates are saved.

   Note: *Click **Exit** to return to the main window.*

Setting Test Type List

The list of test types can be set in Configuration Manager for display, reports, or selection. Select **Test Type** from the **Master File Maintenance** menu to display a dialog box for viewing the Test Type Maintenance records for resident tests. These records show the "hole code" used to identify each test on the instrument and the correlation equation used for that test.



***Note**: Only the **Inactive** flags can be modified. This modification does not affect assay availability on the instrument.*

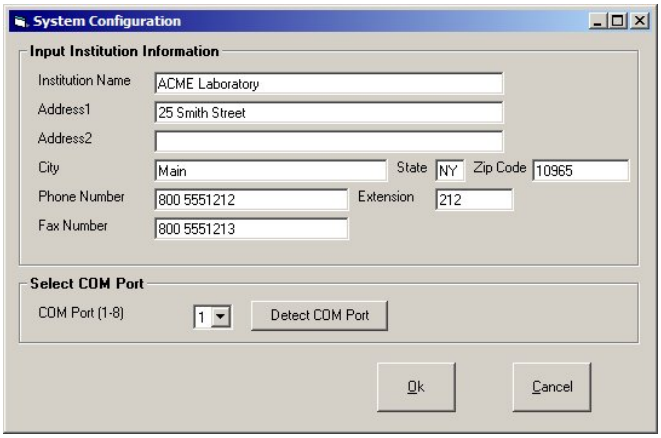
CONFIGURATION MANAGER UTILITIES

The HEMOCHRON *Configuration Manager* Utilities allow supervisors to perform certain functions of the HCM database:

Function	Description
System Configuration	Update institution name, address, and contact information. Enter the PC COM port used, or automatically detect it.
Security	Update or delete HCM user records, including user name file, password, or security level.
Set Real Time Clock	Synchronize the time between an instrument and the PC.
Purge Configuration Data	Remove a configuration file from the database.
Rebuild Database	Compress and repair the specified tables. (**Compress** reduces the size of database files. **Repair** re-indexes each table).
Convert HCM Data from Ver 1.0 to 1.1	Converts data from HEMOCHRON *Configuration Manager* V1.0 to V1.1.

Updating Laboratory Information and/or PC COM Port

1. Select **System Configuration** from the **Utilities** menu. The System Configuration dialog box is displayed:



Note: *The System Configuration dialog box is automatically displayed for entry of information during installation of HEMOCHRON Configuration Manager Software (page 26).*

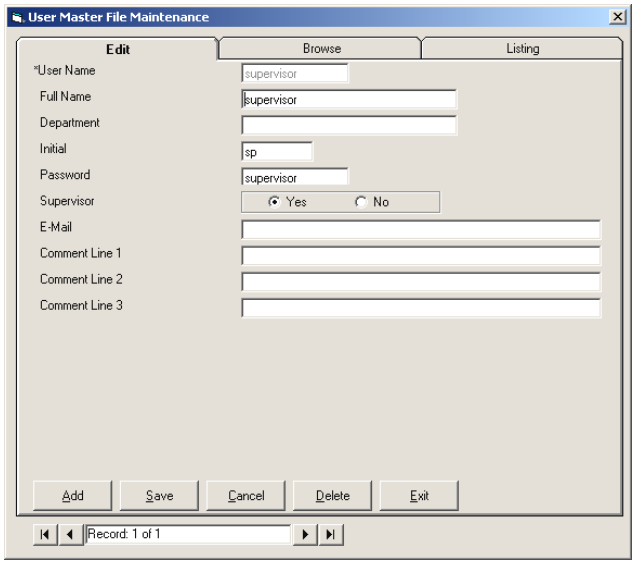
2. Enter the institution name, address, and/or contact information.
3. Click **Detect COM Port** to automatically detect the PC COM port that is being used. Alternately, click the drop-down arrow in the COM Port box and select the number of the COM port used.
4. Click **OK**. The information is saved.

Adding a User

The supervisor can add a new user to the table of operators of HEMOCHRON *Configuration Manager*. The new user will be assigned a password and access level.

> ***Note**: Any user can perform all operations until at least one user with an access level of Supervisor is defined. Once a supervisor is defined, only the supervisor can create and edit any files in Configuration Manager. All other users will only be allowed to view and print.*

1. Select **Security** from the **Utilities** menu. The User Master File Maintenance dialog box is displayed:



2. Click **Add** to display a blank user information form.
3. Enter the user name, password, e-mail address and other information.

   ***Note:** Entries are not case-sensitive.*
4. Select **Yes** in the Supervisor field if the user is to have supervisor-level access.
5. Click **Save**. The new user record is saved.

Updating a User Record

The supervisor can modify or delete a record for an existing user.

1. Select **Security** from the **Utilities** menu. The User Master File Maintenance dialog box is displayed listing information for the first user record in the database.

   Note: *The record number and total number of records in the database are displayed at the bottom of the dialog box.*
2. Use the scroll buttons at the bottom of the dialog box to display the record to be updated.
3. Update the name, password or access level as needed. Click **Delete** to delete the user record.

   Note*: Entries are not case-sensitive. The User Name field cannot be changed. To change User Name, delete the record and add a new record for the new User name.*
4. Click **Save**. The updates are saved.

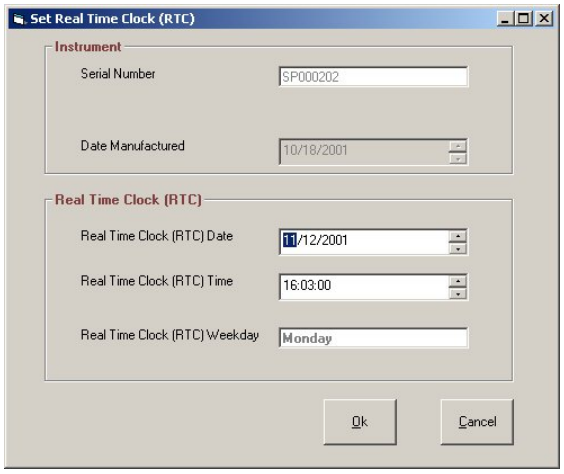
   Note: *Click* ***Exit*** *to return to the main window.*

   Important: *The user name "Supervisor" cannot be deleted from the database; however the password can be changed.*

Setting the Real Time Clock

The time clock of the HEMOCHRON Jr. *Signature+* instrument must be synchronized with that of the HEMOCHRON *Configuration Manager* PC so that correct starting times are used for system lockouts.

1. Connect the instrument to the PC (see page 26).
2. Start HEMOCHRON *Configuration Manager* (see page 27).
3. Select **Real Time Clock** from the **Utilities** menu. The Set Real Time Clock (RTC) dialog box is displayed:

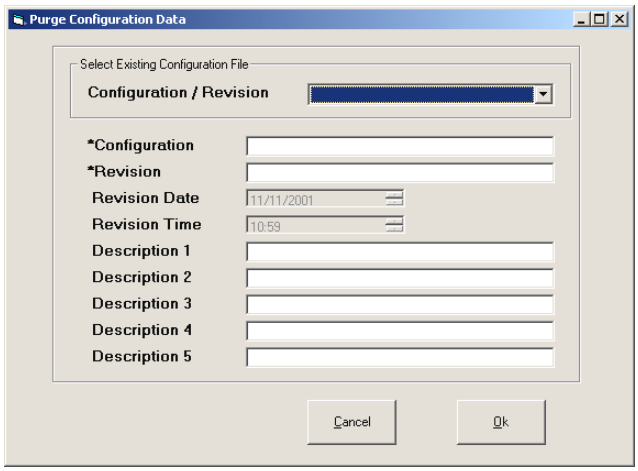


   Note: *The Instrument information is read-only and cannot be changed by the user.*
4. Set the Real Time Clock date and time using the up and down arrow keys.
5. The day of the week in the Real Time Clock Weekday field changes when the date is entered.
6. Click **OK** to synchronize the clocks.

Purging Configuration Data

An existing configuration file can be removed from the *Configuration Manager* database. A record of the file removal is maintained in the audit trail.

1. Select **Purge Configuration Data** from the **Utilities** menu. The Purge Configuration Data dialog box is displayed:



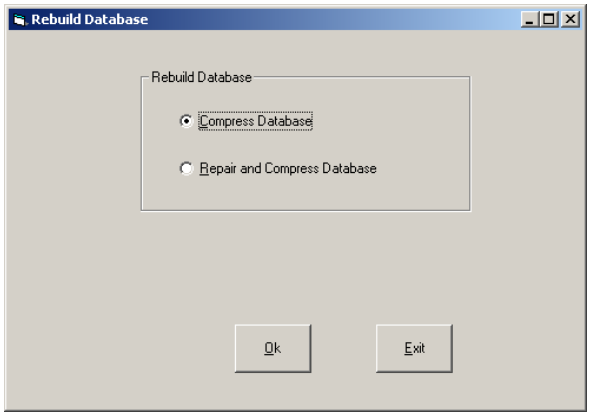
2. Use the drop-down arrow to select the configuration file that is to be purged. The information for the configuration file is displayed.

   Note: *The information is read-only and can not be changed by the user.*

3. Click **OK**. The selected configuration file is purged from the database.

Rebuilding the Database

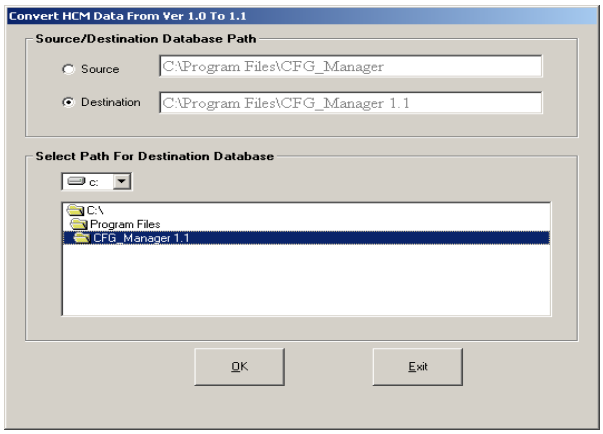
1. Select **Rebuild Database** from the **Utilities** menu. The Rebuild Database dialog box is displayed:



2. Select the operation (**Compress Database**, or **Repair and Compress Database**) that is to be performed.
3. Click **OK**. The databases are repaired and/or compressed.

Converting the Database

1. Select **Convert HCM Data from Ver 1.0 to 1.1** from the **Utilities** menu. The Convert HCM Data from Ver 1.0 to 1.1 dialog box is displayed:



Note: *The source and destination paths are shown. These cannot be modified.*

2. Click **OK** to start the conversion. A progress bar is displayed during the conversion, and a message box confirms the data is successfully converted.

Configuration Manager Error Messages

Problem	Cause	Corrective Action
CHKSUM error during data transfer	Other software applications are open during data transfer.	Close all applications including anti-virus programs during communications.
Communication error/ Initialization error	Incorrect cable is used or cable is not completely connected.	Ensure proper cable is being used. Check cable connections.
No COM Port	No COM Port available.	Use HCM to detect available COM Port
Text crowded / Overlapping on screen	Older computer graphics card	Does not affect program. Printouts will be correct.

Instrument Error Messages

The error messages that may be displayed while operating the HEMOCHRON Jr. *Signature+* instrument are listed below. The probable cause and corrective action are shown for each message.

Some messages designate a test or sample fault. This message is included in the printed results for the affected sample. A list of these messages can be found in *Acronyms for Error Messages* on page 25.

If needed, contact ITC Technical Service by phone at +1-732-548-5700, by FAX at +1-732-548-9824, or by e-mail at techservice@itcmed.com.

Error Message	Cause	Corrective Action
RTC....FAULT	Can not communicate with external Real Time Clock.	Contact ITC Technical Service.
CHARGE BATTERY	Battery power depleted below predetermined level.	Connect to AC/DC Power Module and charge battery for 16 hours.
BATTERY DEAD!	Battery is discharged.	Charge battery for 16 hours. If message persists, contact ITC Technical Service.
Heater Too Cool	Incubator remained below 36 °C after 90 seconds of warming on external power or for up to 150 seconds on battery.	Repeat test, then charge battery. If message persists, contact ITC Technical Service.
Heater Too Hot	Incubator exceeded 38 °C for 2.5 seconds.	Repeat test with new cuvette. If message persists, contact ITC Technical Service.
Detector blocked	Light path between LED and detectors is blocked.	Repeat test with new cuvette. If message persists, contact ITC Technical Service.
Sample Pos Fault	Sample has moved outside of testing area in cuvette.	Contact ITC Technical Service.
ASSAY LOCKED CALL SUPERVISOR	The QC failure limit has been exceeded.	Remove the cuvette. Contact the supervisor.

Error Message	Cause	Corrective Action
MACHINE LOCKED CALL SUPERVISOR	The EQC failure limit has been exceeded.	Contact the Supervisor.
Sample Not Seen	Sample has not reached front detector in specified time period.	Repeat test with new cuvette. If message persists, contact ITC Technical Service.
Cuvette Removed	Cuvette was prematurely removed from instrument while testing in progress.	Repeat test with new cuvette.
Sample Too Large/ Sample Too Small	Excess or insufficient sample.	Repeat test with new cuvette.
Premature Sample	Sample was detected at front detector before specified time period. May occur if sample is added before pump-priming sequence is complete.	Repeat test with new cuvette. If message persists, contact ITC Technical Service.
HARDWARE FAULT	Electrical disturbance. This may be caused by equipment or devices such as centrifuges, etc.	Repeat test using different AC outlet location.
MEMORY FAULT	Malfunction in the computer's memory.	Contact ITC Technical Service.
START Timed Out	START key was not pressed within 5 minutes after entering ready mode.	Remove cuvette and repeat test with new cuvette.
COD=	Cuvette cannot be identified by instrument.	Remove cuvette and repeat test with new cuvette.
Invalid code	Invalid correlation data entered by Operator.	Re-enter information.
No Data Stored	Operator attempted to print data when none was stored in database.	N/A
Use new cuvette	Used cuvette was reinserted into instrument. Occurs if cuvette channel is blocked or if sample is added before pump priming sequence is complete.	Remove cuvette and repeat test with new cuvette.
Access Denied	Date/Time cannot be changed if QC Lockout is required, or Date/Time function is denied through Configuration Manager.	Supervisor needs to reconfigure instrument using HCM.
Disallowed Assay	Assay performance has been prohibited via *Configuration Manager*.	Supervisor needs to reconfigure instrument using HCM.
Cannot erase DB	Erasing patient and/or QC database is not allowed.	Supervisor needs to reconfigure instrument using HCM.

Error Message	Cause	Corrective Action
INR < 0.8 INR > 10.0 APTT < 20	Test result is outside clinical range.	Repeat test with new cuvette.
Out of Range-Lo	Test result is outside clinical range. Sample has clotted prematurely, or did not mix correctly in cuvette. Bubbles may be present.	Repeat test with new cuvette.
Out of Range-Hi	Test result is outside clinical range.	Repeat test with new cuvette.
Check Time/Date	Low Battery or RTC has lost its Time/Date Tracking.	Enter or Verify Time & Date. Charge Battery.
Dark Photo Fault	Hardware malfunction.	Contact ITC Technical Service.

SERVICE AND MAINTENANCE

Routine Maintenance

Inspect and clean the cuvette opening as required. Remove residual dried blood or other foreign matter using water moistened cotton swabs.

Remove any residual water with dry cotton swabs. If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% dilution of household bleach in water. Wipe instrument with a water-dampened cloth to remove residual bleach from the plastic surfaces.

Apply solution to clean and disinfect areas contaminated with blood. DO NOT use solvents or strong cleaning solutions as they may damage the instrument's plastic components. Routine maintenance other than cleaning normally is not required.

Service

The HEMOCHRON Jr. *Signature+* instrument is almost completely self-monitoring.

It monitors internal circuitry and reports problems to the display screen automatically. Malfunctions are indicated by error messages detailed in the section "Troubleshooting."

Battery Care

To optimize battery life, it is recommended that the HEMOCHRON Jr. *Signature+* instrument be run on its battery during the day. It can be plugged into a standard AC outlet overnight to allow the batteries to recharge. The life of the nickel metal hydride battery is optimized when the battery is exercised in this manner.

A fully charged battery will operate as defined in the *Operation* specifications section on page 10.

When the batteries are drained to the point that valid testing cannot be performed, the instrument will display "CHARGE BATTERY" (see "Troubleshooting"). At this point, the instrument must be plugged in for operation and recharging. Once plugged into an AC outlet, the instrument can be used immediately.

Instrument Disposal

If disposal is necessary, follow local regulations for disposal of electronic devices.

SAFETY STANDARDS

The HEMOCHRON Jr. *Signature+* instrument complies with the following safety standard requirements and directives:

CSA C22.2. 601.1.	Medical Electrical Equipment – General Requirements for Safety
EN 60601-1 / IEC 60601-1/ UL 60601-1	Medical Electrical Equipment – General Requirements for Safety
EN 60601-1-2 / IEC 60601-1-2	Medical Electrical Equipment – Part 1-2 – General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
EN 61000-3-2	Electromagnetic Compatibility – Limits – Limits for Harmonic Current Emissions
EN 61000-3-3	Electromagnetic Compatibility – Limits – Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-voltage Supply Systems
EN 55011	Industrial, Scientific and Medical (ISM) Radio Frequency Equipment – Radio Disturbance Characteristics – Limits and Methods of Measurement
EN 61326	Electrical Equipment for Measurement, Control and Laboratory Use – EMC Requirements
Directives: 89/336/EEC and as amended by 91/263/EEC, 92/31/EEC, 93/68/EEC, 98/13/EC, and 98/79/EC.	

All the relevant documentation is kept on file at ITC in Edison, NJ.

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